## REMARKS

Rejection of benefit of earlier filing date under 35 USC 120 and 119(e):

Benefit of the earlier filing date of US provisional application 60/167,836 and non-provisional application 09/234,606 has been denied. Applicants respectfully disagree.

With respect to US provisional application serial number 60/167,836, Applicants believe that clear written support for claim 1 of this amended application can be found on page 6 line 39 bridging to page 7 line 7 and page 9 lines 2-8. This section of the provisional application describes the formation of complexes containing nucleic acids and cyclodextrin polymer. 60/167,836 states that "association between a polymer composed of cyclodextrins and a cationic amphiphile will result in a polycation that may interact with DNA", i.e. a noncovalent amphiphilic polyelectrolyte as described in the instant application. Both the provisional application and the instant application teach that the noncovalent amphiphilic polyelectrolyte may be positively or negatively charged and that binding of amphiphiles by the polycyclodextrin polymer is reversible.

With respect to US non-provisional application serial number 09/234,606, Applicants believe that clear written support for claim 1 of this amended application can be found on page 4 lines12-16 and lines 23-24, page 5 lines 20-25, and page 14 lines 8-9. Both 09/234,606 and this amended application describe the formation of a non-covalent polyion.

For example, in 09/234,606, a process by which a neutral polymer can be made cationic through the binding of cations to chelating groups in the polymer is described. The resultant noncovalent cationic polymer is then able to form a complex with DNA which may then be used to deliver the DNA to a cell. In this amended application, a process by which a neutral polymer can be made cationic through the binding of amphiphilic cations to amphiphile binding agents in the polymer is described. The resulting noncovalent cationic polymer is then able to form a complex with DNA which may then be used to deliver the DNA to a cell. Both applications describe the formation of charged polymers in which the charge is noncovalently associated with the polymer. Because the charge is associated non-covalently with groups on a polymer, the charge on the polymer is reversible.

Rejection of claims under 35 U.S.C. 102:

Claims 1-20 have been rejected under 35 USC 102(b) as being anticipated by Hung (WO 97/16169). Applicants have amended the claims to obviate the rejection.

Applicants have amended the claims to specify the association of a polynucleotide with a noncovalent amphiphilic polyelectrolyte which is described in the specification on page 24 lines 9-26. Cyclodextrin liposomes are mentioned by Hung, but no description of cyclodextrin liposomes is provided. A search of the literature suggests that a cyclodextrin liposome is a standard liposome in which cyclodextrin in encapsulated into the interior space of the membrane enclosed vesicle. The literature does not describe binding of lipid to cyclodextrin to form a noncovalent amphiphilic electrolyte as Applicants have disclosed.

Rejection of claims under 35 U.S.C. 103:

Claims 1-20 have been rejected under 35 USC 103(a) as being unpatentable over Sankaran (WO96/08235), Kim (US 5,759,573) or Kosak (US 6,048,736) taken with Niven (US 6,022,737), Ye (WO 99/12523), or Hung(WO 97/16169). Applicants have amended the claims to obviate the rejection.

Specifically, Applicants have amended the claims to specify the association of a polynucleotide with a noncovalent amphiphilic polyelectrolyte which is described in the specification on page 24 lines 9-26.

Sankaram describes the benefits of encapsulating solutes in a membrane enclosed vesicle, a liposome, to act as an osmotic spacer. Sankaram lists a number of molecules that can be used for this propose, including cyclodextrin. Similarly, Kim describes the encapsulation of cyclodextrin into the aqueous phase of a liposome. Applicants do not believe that either Sankaram nor Kim provide teaching on the formation of a noncovalent amphiphilic polyelectrolyte.

Kosak describes the well known property of using cyclodextrin as a drug carrier, especially hydrophobic drugs, wherein the drug is directly bound within the cavity of the cyclodextrin. Kosak further describes improved pharmacokinetics of drug release when the cyclodextrin is present as a poly-cyclodextrin polymer. However, Kosak teaches that the drug is bound directly by the cyclodextrin. In contrast, Applicants describe the formation of a noncovalent amphiphilic polyelectrolyte which can form a complex with a polynucleotide via the noncovalent charge associated with the polyelectrolyte. Applicants suggest that neither Sankaram, Kim, or Kosak provides any teaching on the formation of a noncovalent amphiphilic polyelectrolyte.

The Examiner's objections and rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendment and arguments, it is submitted that claims 1, 2, 4, 5, 7-15, 17, 18, and 20 should be allowable.

Respectfully submitted,

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I hereby certify that this correspondence is being sent by facsimile transmission to: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on this date: October 13, 2003.

Kirk Ekena